



UNITED STATES PATENT AND TRADEMARK OFFICE

CH
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,930	04/16/2004	Robert S. Neuwirth	ABL-101	9014
7590 OLSON & HIERL, LTD. 36th Floor 20 North Wacker Drive Chicago, IL 60606	08/22/2007		EXAMINER ARNOLD, ERNST V	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 08/22/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,930	NEUWIRTH, ROBERT S.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 May 2007.
- 2a) This action is FINAL.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 14-30 and 37-39 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 14-30 and 37-39 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claims 14-30 and 37-39 are pending. The Examiner has a new ground of rejection and regrets another non-final rejection.

Withdrawn rejections:

Claims 19, 20, 24, 25, 26, 28, 30 and 37 were rejected under 35 U.S.C. 102(b) as being anticipated by Tsukisaka et al. (JP 05345010A). Applicant asserted that the beads of Tsukisaka et al. do not bear silver nitrate but rather a water insoluble organic polymer silver salt. The Examiner finds this persuasive and withdraws the rejection.

Claims 14-30 and 37 were rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukisaka et al. (JP 05345010A) in view of Neuwirth (WO 96/40171) and Block (Disinfection, Sterilization and Preservation 1977, pages 395-407) and Hirai et al. (US 5,213,895) and Siiman et al. (US 5,552,086). Applicant's arguments are persuasive and the rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a delivery vehicle for silver nitrate in the treatment of menorrhagia, does not reasonably provide enablement for a delivery vehicle for all silver ion releasing compounds for the treatment of menorrhagia. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, that a silver nitrate releasing bead can necrose tissue in 5-20 minutes (page 10, Table 1). However, Applicant is purporting to use all silver ion releasing compounds including water soluble organic silver salts such as silver acetate and silver lactate as well as silver permanganate and perchlorate.

2) Nature of the invention

The nature of the invention is directed to silver nitrate releasing beads for the treatment of menorrhagia.

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators directing scientific research and development in this particular technological area possess an Ph.D. in a scientific discipline such as organic synthetic chemistry, polymer chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like.

4) State of, or the amount of knowledge in, the prior art

The art teaches that silver nitrate paste, as well as other caustic agents such as zinc chloride, phenol and iodine, can be used to cauterize uterine tissue (US 6,187,346; abstract; column 9, lines 41-45 and claim 1). The art teaches that insoluble silver chloride does not cauterize tissue (US 6,187,346; column 9, lines 22-40). **There are two important points: 1) the solubility of the silver salt is critical for action; and 2) the identity of the counter anion may also be critical for action since only silver nitrate is taught in the art.**

5) Level or degree of predictability, or a lack thereof, in the art

The art teaches that different silver salts have different solubility's in water. Silver nitrate has a solubility of about 216 g/100 ml of water at 20 C while some organic silver salts such as silver acetate only has a solubility of about 1 g/100 ml of water at 20 C which is similar to silver permanganate which has a solubility of about 0.9 g/100 ml of water at 20 C. Silver carbonate is even less soluble and only has a solubility of about 0.00348 g/100 ml of water at 20 C (Wikipedia: solubility Table: silver).

US 3,930,000 teaches the slow release of silver ions from a silver zinc allantoinate (abstract).

Art Unit: 1616

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. Although the instant specification discloses silver nitrate releasing beads, it remains silent on other silver salts that would necrose tissue in the treatment of menorrhagia. Applicant teaches water soluble silver salts but it appears that only the highly soluble silver nitrate provide the proper effect.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to all silver ion releasing compounds.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to conduct a myriad number of experiments comprising picking and choosing silver salts; coating beads with the salt and testing the tissue necrosing ability of the beads without any further guidance provided by Applicant. One would have to balance the solubility of the salt and the identity of the counter anion as related to the desired function. Essentially, one of ordinary skill in the art has to figure out how to do this themselves. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in

return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-30 and 37-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*.

While all of the factors have been considered, only those required for a *prima facie* case are set forth below.

The claims are drawn to a delivery vehicle for a silver ion releasing compound for use in the treatment of menorrhagia.

The specification discloses silver nitrate, silver acetate, silver lactate, silver perchlorate and silver permanganate as the silver ion releasing compounds.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of the claim indicates that these claims are drawn to a genus, i.e., any compound that releases silver ion. There are only a five silver salts explicitly disclosed.

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses any and all compounds that release silver ions such as silver glasses, silver zeolite, silver-polymer conjugates, etc... There is substantial variability among the species of compounds encompassed within the scope of the claims because the silver salts recited are only several salts amongst an entire class of salts that can have widely differing structures and corresponding biological activities. Further, defining the compound in functional terms would not suffice in the absence of a disclosure of structural features or elements of the compound that would have the stated function. Applicant is describing what the compound does rather than what it is.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Consequently, the Examiner notes that the claimed invention which is drawn to a genus of compounds that may be adequately described if there is a (1) sufficient description of a representative number of species, or (2) by disclosure of relevant,

identifying characteristics sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. Here, the specification discloses only a couple of silver salts and the only examples are with silver nitrate. Since the claimed genus encompasses compounds yet to be discovered, the disclosed structural feature does not constitute a substantial portion of the claimed genus. Therefore, the disclosure of silver nitrate, silver acetate, silver lactate, silver perchlorate and silver permanganate as the silver ion releasing compounds does not provide an adequate description of the claimed genus.

Weighing all the factors, the breadth of the claims reading on drugs yet to be discovered, the lack of correlation between structure and function of the drugs, level of knowledge and skill in the art, one of ordinary skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of compounds that release silver ions. At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work. Neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms, that are common to the genus. That is, the specification provides neither a representative number of silver ion releasing compounds to describe the claimed genus, nor does it provide a description of structural features that are common to the compounds. In essence, the specification simply directs those skilled in the art to go figure out for themselves the silver ion releasing compounds.

The written description requirement is not satisfied. The Examiner needs to know the identity of the silver ion releasing compound.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 15 recite the limitation " the water soluble inorganic silver salt ". There is insufficient antecedent basis for this limitation in the claim.

Claims 19-26, 28-30 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 19 recites "at least about 75 percent by weight silver nitrate". "At least" is a static point and "about" is a dynamic point thus making the amount unclear and indefinite. Claims 20-26, 28-30 and 37-39 are rejected as indefinite because they are dependent on an indefinite base claim.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616



Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600